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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,574

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EXAMINER

HAND, MELANIE JO

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,574	Applicant(s) SIGURJONSSON ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-16, 18-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 18-20, 22, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2007 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 12, 14-16, 18-20, 22 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant states in the Remarks filed November 29, 2007 on page 7 that Figures 17, 18 and "the corresponding sections in the specification" are sufficient support for the newly added

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limitation of a facing layer that is a hydrophobic silicone gel having an uninterrupted thickness. Examiner disagrees. No mention is made in these sections of the specification, specifically Page 27, ¶3 – Page 28, ¶3, of the thickness of the skin adherent facing layer. Further, this citation includes a reference to different methods for applying the material of the claimed facing layer which can produce an uninterrupted or interrupted thickness. The term “uninterrupted thickness”, since it is not defined in the disclosure, is interpreted herein as meaning uniform thickness. In light of this interpretation, it is unclear how the claimed facing layer can have an uninterrupted thickness when the layer also defines a pattern of through-extending apertures along an apertured portion thereof.

Claim Interpretation

5. The term “uninterrupted thickness” in claim 23 is not defined in the disclosure. Hence, the term is interpreted herein for examination purposes as meaning “of uniform thickness”.

Claim Objections

6. Claim 19 is objected to because of the following informalities: claim 19 refers to “the first facing layer of the backing layer”. The first facing layer is not disclosed or claimed to be a structural part or feature of the backing layer, rather they are disclosed and claimed as being two physically separate entities. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 12-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snedeker (U.S. Patent No. 4,664,106) in view of Fabo (WO 87/05206).

With respect to **claim 12**: Snedeker teaches a wound dressing having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface, the dressing comprising: an absorbent core in the form of wound covering 14 defining opposed proximal and distal surfaces, the distal surface including a central portion and a border portion. A liquid impervious, vapor permeable backing layer is present in the form of film 10 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 10 extending over the distal surface of the absorbent core 14, and defining a border portion in the form of offal portion 15 extending beyond and surrounding peripheral edges of the absorbent core 14, the distal surface of the backing layer 10 defining the backside surface of the wound dressing. A first skin adherent facing layer, specifically the portion of adhesive layer 19 which lies outside perforation line 11 and overlies offal portion 15, is considered herein to necessarily be discontinuous with the rest of adhesive layer 19 due to the formation and presence of the perforation line 11. This outside area will be referred to herein as 19 (15). First skin-adherent facing layer 19 (15) is directly secured only to the proximal surface of the border portion 15 of the backing layer 10 and surrounds the peripheral edges of the absorbent core 14. A proximal surface of the first facing layer 19 (15) defines a portion of the bodyside surface of the wound dressing, inasmuch as it is covered only by release liner offal portion 25 which is removed prior to application to expose portion 15 which adheres to the skin. A second perforated facing layer in the form of a second area of adhesive is directly secured to and coextensive with the proximal surface of the absorbent core 14 and is perforated by perforation

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line 11. A proximal surface of the second facing layer necessarily defines a portion of the bodyside surface of the wound dressing, as it is covered only by release liner 24 which is removed in a similar manner as release liner offal portion 25 to expose the adhesive layer present on core 14 that allows it to adhere to the skin upon pressing by the user. The proximal surface of the second facing layer is generally co-planar with the proximal surface of the first facing layer, a periphery of the second facing layer being contiguous with a periphery of the first facing layer, wherein the periphery is defined by perforation line 11. The bodyside surface of the wound dressing consists of the proximal surfaces of the first and second facing layers. ('106, whole document)

Snedeker does not teach that the second facing layer is composed of a skin adherent hydrophobic silicone gel. Fabo teaches a wound dressing having a skin-adherent adhesive thereon comprised of a hydrophobic silicone gel. Fabo teaches that such an adhesive will stick to dry skin while not adhering to wound tissue, thus preventing potential ripping or injury of healthy tissue surrounding the wound or re-injuring healing wound tissue. Thus it would be obvious to one of ordinary skill in the art to modify the second facing layer of Snedeker that is coextensive with absorbent pad 14 such that said second layer is a skin-adherent hydrophobic silicone gel as taught by Fabo to ensure that the absorbent pad 14 and the dressing as a whole remains in position over the wound site without adhering to healing tissue at the wound site or healthy tissue surrounding the wound site. ('206, Abstract, Page 2, lines 24-27)

With respect to **claim 14**: The border portion 15 of the backing layer 10 of Snedeker is substantially parallel with the distal surface of the absorbent core 14. ('106, Fig. 3)

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With respect to **claim 15**: The border portion 15 of the backing layer 10 of Snedeker includes at least two opposed elongate sections each opposed elongate section extending from a corresponding side of the absorbent core 14. ('106, Figs. 1,2)

With respect to **claim 16**: The first facing layer 19/15 taught by Snedeker is an acrylic adhesive, which is a pressure-sensitive adhesive. (Col. 3, lines 8-12)

With respect to **claim 18**: The first facing layer 19/15 is taught by Snedeker to be sufficiently thin so that the wound can breathe through the adhesive material 19 and through polymeric film 10", i.e. first facing layer 19/15 is also sufficiently porous so as not to occlude moisture transmission through the backing layer 10. (Col. 3, lines 12-16)

With respect to **claim 19**: With regard to the limitation "the first facing layer of the backing layer has greater skin adherence properties than the second facing layer", the combined teaching of Snedeker and Fabo teaches a first facing layer comprising a pressure-sensitive adhesive and a second facing layer comprising a hydrophobic silicone gel, which are the materials disclosed by applicant as the materials for the first and second facing layers, thus the first facing layer of the article of the combined teaching of Snedeker and Fabo inherently has greater skin adherence properties than the instant second facing layer of the article of the combined teaching. The motivation to modify the article of Snedeker so as to have a second facing layer comprising the hydrophobic silicone gel is stated *supra* with respect to claim 12.

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9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snedeker ('106) in view of Fabo ('206), as applied to claims 12-19 and 22 above, and further in view of Bogart (U.S. Patent No. 5,512,041).

With respect to **claim 20**: Neither Snedeker nor Fabo teaches peripheral edges of an absorbent core having a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Bogart teaches a wound dressing having an absorbent core with a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Since the articles of the combined teaching of Snedeker and Fabo and Bogart seek to solve a similar problem in the art (i.e. provide a wound dressing for absorbing wound exudates), it would be obvious to one of ordinary skill in the art to modify the article of Abuelyaman such that the absorbent core has a bevel as taught by Bogart with a reasonable expectation of success to provide an wound dressing having an absorbent core that is shaped suitably for application as part of a wound dressing.

With respect to **claim 22**: Snedeker teaches a wound dressing having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface, the dressing comprising: an absorbent core in the form of wound covering 14 defining opposed proximal and distal surfaces, the distal surface including a central portion and a border portion. A liquid impervious, vapor permeable backing layer is present in the form of film 10 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 10 extending over the distal surface of the absorbent core 14, and defining a border portion in the form of offal portion 15 extending beyond and surrounding peripheral edges of the

absorbent core 14, the distal surface of the backing layer 10 defining the backside surface of the wound dressing. ('106, whole document)

Snedeker does not teach a continuous skin-adherent facing layer composed of a skin adherent hydrophobic silicone gel and directly secured to both the proximal surfaces of absorbent core 14 and the border portion 15 of the backing layer 10. Fabo teaches a wound dressing having a skin-adherent adhesive thereon comprised of a hydrophobic silicone gel. Fabo teaches that such an adhesive will stick to dry skin while not adhering to wound tissue, thus preventing potential ripping or injury of healthy tissue surrounding the wound or re-injuring healing wound tissue. Thus, it would be obvious to one of ordinary skill in the art to modify the second facing layer of Snedeker that is coextensive with absorbent pad 14 such that said second layer is a skin-adherent hydrophobic silicone gel as taught by Fabo to ensure that the absorbent pad 14 and the dressing as a whole remains in position over the wound site without adhering to healing tissue at the wound site or healthy tissue surrounding the wound site. The facing layer of the combined teaching of Snedeker and Fabo thus defines the entirety of the bodyside surface of the instant wound dressing. ('206, Abstract, Page 2, lines 24-27)

Snedeker also does not teach that the facing layer defines a pattern of through extending apertures only along the portion thereof bounded by the peripheral edges of the absorbent core. Fabo teaches that the instant skin-adherent silicone gel facing layer also defines a pattern of through-extending apertures in the form of holes 5. Fabo teaches that these holes admit the passage of fluid and air from the wound through, thus providing breathability to the wound for optimal healing. Thus, it would be obvious to one of ordinary skill in the art to modify the article of Snedeker so as to comprise the continuous skin adherent facing layer of Fabo defining through-extending apertures only along the portion of the layer bounded by its peripheral edges to admit the passage of fluid and air from a wound to provide optimal healing.

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The apertures of the facing layer of the article of the combined teaching of Snedeker and Fabo are formed irrespective of the proximal surface of the absorbent core because they are only formed as part of the facing layer. ('206, Abstract, Page 3, lines 16-24, Page 4, lines 9-15, 23-30)

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snedeker ('106) in view of de Jong et al (U.S. Patent Application Publication No. 2003/0120229) and further in view of Fabo ('206).

With respect to **claim 23**: Snedeker teaches a wound dressing having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface, the dressing comprising: an absorbent core in the form of wound covering 14 defining opposed proximal and distal surfaces, the distal surface including a central portion and a border portion. A liquid impervious, vapor permeable backing layer is present in the form of film 10 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 10 extending over the distal surface of the absorbent core 14, and defining a border portion in the form of offal portion 15 extending beyond and surrounding peripheral edges of the absorbent core 14, the distal surface of the backing layer 10 defining the backside surface of the wound dressing. The portion of adhesive layer 19 corresponding to the border portion, i.e. adhesive area 19/15, has a generally smooth surface. ('106, whole document)

Snedeker does not teach a polymeric foam-based absorbent core. However the use of such polymeric foams as absorbent core materials is well known in the art of wound dressings as supported by de Jong ('229, ¶0007), therefore it would be obvious to one of ordinary skill in

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the art to modify the wound dressing of Snedeker such that the core 12 is comprised of polymeric foam based absorbent core with a reasonable expectation of success to ensure that the wound dressing aptly provides the function of absorbing wound exudates.

Snedeker does not teach a continuous skin-adherent facing layer composed of a skin-adherent hydrophobic silicone gel having an uninterrupted thickness. Fabo teaches a wound dressing having a skin-adherent adhesive thereon comprised of a hydrophobic silicone gel having uninterrupted thickness as the term is understood by the examiner. (see the "Claim Interpretation" section of this action) Fabo teaches that such an adhesive will stick to dry skin while not adhering to wound tissue, thus preventing potential ripping or injury of healthy tissue surrounding the wound or re-injuring healing wound tissue. Thus, it would be obvious to one of ordinary skill in the art to modify the second facing layer of Snedeker that is coextensive with absorbent pad 14 such that said second layer is a skin-adherent hydrophobic silicone gel as taught by Fabo to ensure that the absorbent pad 14 and the dressing as a whole remains in position over the wound site without adhering to healing tissue at the wound site or healthy tissue surrounding the wound site. The facing layer of the combined teaching of Snedeker and Fabo thus defines the entirety of the bodyside surface of the instant wound dressing. ('206, Abstract, Page 2, lines 24-27)

Snedeker also does not teach that the facing layer defines a pattern of through extending apertures along an apertured portion thereof adjacent to the distal surface of the absorbent core and bounded by the peripheral edges of the absorbent core. Fabo teaches that the instant skin-adherent silicone gel facing layer also defines a pattern of through-extending apertures in the form of holes 5. Fabo teaches that these holes admit the passage of fluid and air from the wound through, thus providing breathability to the wound for optimal healing. Thus, it would be obvious to one of ordinary skill in the art to modify the article of Snedeker so as to

comprise the continuous skin adherent facing layer of Fabo defining through-extending apertures only along the portion of the layer bounded by its peripheral edges to admit the passage of fluid and air from a wound to provide optimal healing. The apertures of the facing layer of the article of the combined teaching of Snedeker and Fabo are formed irrespective of the proximal surface of the absorbent core because they are only formed as part of the facing layer. ('206, Abstract, Page 3, lines 16-24, Page 4, lines 9-15, 23-30)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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February 13, 2008
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Examiner, Art Unit 3761

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